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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,477	01/10/2002	Jennifer L. Hillman	PF-0401-2 DIV	3188

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,477	HILLMAN ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-2, 17, 18, drawn to a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 530, subclass 350.

Group 2. Claims 3-7, 9-10, 12-13, 46, 48-56, drawn to a polynucleotide encoding a polypeptide of amino acid sequence set forth in SEQ ID NO:1, a vector, a host cell and a method of producing the polypeptide, classified in Class 435, subclass 69.1.

Group 3. Claim 8, drawn to a transgenic organism comprising a polynucleotide encoding a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 800, subclass 21.

Group 4. Claims 11, 31, 32, 34, 36-43, drawn to an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 530, subclass 387.1.

Group 5. Claims 14-16, drawn to a method of detecting a polynucleotide encoding an polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 435, subclass 6.

Group 6. Claim 19, drawn to a method of treatment by administering a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 514, subclass 2.

Group 7. Claims 20, 23, 26, 27, drawn to a method of screening a compound which is an agonist or antagonist of a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 8. Claim 21, drawn to an agonist to a polypeptide of amino acid sequence set forth in SEQ ID NO:1, Class and subclass undeterminable.

Group 9. Claim 24, drawn to an antagonist to a polypeptide of amino acid sequence set forth in SEQ ID NO:1, Class and subclass undeterminable.

Group 10. Claim 22, drawn to a method of treatment by administering an agonist to the polypeptide of amino acid sequence set forth in SEQ ID NO:1, Class and subclass undeterminable.

Group 11. Claim 25, drawn to a method of treatment by administering an antagonist to the polypeptide of amino acid sequence set forth in SEQ ID NO:1, Class and subclass undeterminable.

Group 12. Claim 28, drawn to a method of screening a compound which alters expression of a polynucleotide encoding a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 13. Claim 29, drawn to a method of screening for potential toxicity of a test compound on a biological sample comprising the polynucleotide encoding a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 14. Claims 30, 44, drawn to a method of diagnosis of a disease using an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 15. Claim 33, drawn to a method of diagnosis by administering an antibody to the polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 424, subclass 139.1.

Group 16. Claim 35, drawn to a method of detecting a polypeptide of amino acid sequence set forth in SEQ ID NO:1 by administering an antibody, classified in Class 435, subclass 7.1.

Group 17. Claim 45, drawn to a method of purifying a polypeptide of amino acid sequence set forth in SEQ ID NO:1 by using an antibody, classified in Class 530, subclass 412.

Group 18. Claim 47, drawn to a method of generating an expression profile of a sample which contains a polynucleotide encoding an polypeptide of amino acid sequence set forth in SEQ ID NO:1, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4, 8-9, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotide of invention 2 can be used to make hybridization probes or can be used in gene therapy as well as in the production of the specific protein of interest. The protein of invention 2 can be used as a probe, or used therapeutically or diagnostically, e.g. in screening. The antibodies of invention 4 can be used to obtain the polynucleotide of Group 1, and can also be used in diagnostics, e.g. as a probe in immunoassays.

Inventions 2 and 1 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP

§ 806.05(f)). In the instant case, the protein can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions 1 and 6-7, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention 1 can also be used as an antigen in the production of specific antibodies.

Inventions 2 and 5, 18, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of invention I can also be used in production of the protein of interest.

Inventions 4 and 14-15, 16-17 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention 4 can also be used in immunohistochemistry.

Invention 8 and 10 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention 8 can also be used as an antigen in the production of specific antibodies.

Invention 9 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention 9 can also be used as an antigen in the production of specific antibodies.

Inventions 1 and 5, 10-18 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 2 and 6-7, 10-17 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 4 and 5-7, 10-13, 18, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects.

(MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 8 and 5-7, 11-18 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 9 and 5-7, 10, 12-18 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 5-7, 10-18 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
June 15, 2004